IN THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, AND STATE OF CALIFORNIA, *ex rel.* DAVID HONG,

Relator,

v.

EISENHOWER MEDICAL CENTER,

EISENHOWER MEDICAL ASSOCIATES, INC.,

AND

MONICA KHANNA, M.D.,

Defendants.

Civil Action No.: ED CV18-02667 (KKx)

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

COMPLAINT

1. Relator David Hong ("Hong"), M.D., by counsel, brings this action on behalf of the United States of America, the State of California ("California"), and himself under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and the California False Claims Act, Cal. Gov't Code § 12651, *et seq,* against Defendants Eisenhower Medical Center ("EMC") and Eisenhower Medical Associates ("EMA," collectively "Eisenhower") to recover losses sustained by the United States Department of Health and Human Services ("HHS") Centers for Medicare and Medicaid Services ("CMS") and the California Department of Health Care Services ("DHCS" or "California Medi-Cal") due to the Defendants' false claims to Medicare and Medicaid and the creation of false records material to Medicare and Medicaid claims for health services.

I. Introduction

2. Eisenhower Health is a large private health care organization located in the Coachella Valley of Southern California. Dr. David Hong joined Eisenhower in July 2017 as a radiation oncologist and immediately observed a variety of billing and treatment practices that violate the billing guidelines promulgated by Medicare. Dr. Hong raised concerns about these practices, which include misrepresenting medical procedures being performed at Eisenhower by "upcoding" or "unbundling" services, failing to document medical services as required under Medicare guidelines, failing to properly supervise medical treatment, failing to provide competent medical treatment by legitimately credentialed providers, and violating the Anti-Kickback Statute by providing valuable medical supplies to referring physicians. Dr. Hong's concerns were ignored and he left Eisenhower in September 2018.

3. As outlined in more detail below, Eisenhower's deviations from the Medicare and Medicaid guidelines form the basis for numerous federal False Claims Act and California False Claims Act violations.

II. Jurisdiction and Venue

4. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 31 U.S.C. §§ 3732(a) and 3730(b). The Court has supplemental jurisdiction to entertain the claims made on behalf of the State of California pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

5. This Court has personal jurisdiction of the Defendants because the Defendants can all be found in and transact business in the Central District of California.

6. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) because, at all times material and relevant hereto, the Defendants transacted business and resided in the Central District of California.

7. Relator's claims in this Complaint are not based on allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the government is already a party, as enumerated in 31 U.S.C. § 3730(e)(3).

8. To the extent that there has been a public disclosure unknown to the Relator, he is the "original source" and meets the requirements of § 3730(e)(4)(B) and Cal. Gov't Code § 12652(d)(3)(C). Relator has direct and independent knowledge of the information upon which the allegations are based, and has voluntarily provided this information to the government prior to filing this action under seal, as required by 31 U.S.C. § 3730(b)(2) and Cal. Gov't Code § 12652(d)(3)(C).

III. Parties and Other Key Players

9. Relator Dr. Hong was a radiation oncologist at Eisenhower from July 2017 until September 2018.

10. Eisenhower Medical Center is a California nonprofit corporation with its principal place of business in Rancho Mirage, California.

11. Eisenhower Medical Associates, Inc., is a California corporation with its principal place of business located in Rancho Mirage, California.

12. Monica Khanna, M.D., is a radiation oncologist at Eisenhower Medical Center and is, upon information and belief, an employee and/or agent of both Eisenhower Medical Center and Eisenhower Medical Associates, Inc. Dr. Khanna is the Medical Director of Eisenhower BIGHORN Radiation Oncology.

IV. Legal Framework

13. The FCA provides, in part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> [or]
>
> (a)(1)(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.
>
> Is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729. For purposes of the FCA,

> [T]he terms "knowing" and "knowingly"—(A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud

14. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 and 64 Fed. Reg. 47099 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999. The Federal Civil Penalties Adjustment Act Improvements Act of 2015 and its implementing regulations linked FCA civil penalties to inflation. *See* 28 C.F.R. 85.3(a)(9).

15. The California False Claims Act provides, in part, that any person who commits the following enumerated acts is liable for treble damages, civil penalties, and litigation costs:

> (a)(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval[;]
>
> (a)(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim[;]
>
> [or]
>
> (a)(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or to any political subdivision.

Cal Gov't Code § 12651.

16. The California False Claims Act defines "knowing" and "knowingly" as meaning that a person, with respect to information, (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information" and requires no proof of specific intent to defraud. Cal. Gov't Code § 12650(b)(3).

V. Medicare and Medicaid Reimbursement Protocol

17. When hospitals and physicians render services and supplies to Medicare or Medicaid beneficiaries, Medicare or Medicaid, respectively, will reimburse the healthcare provider for those services and supplies, based on set rates.

18. Participating healthcare providers file claims for services or supplies rendered under the Medicare or Medicaid programs. Medicare Part B and Medicaid are medical insurance plans, and Medicare Part D is a prescription drug coverage plan. When a healthcare provider files a reimbursement claim for services rendered, he fills out the 837P standard format electronic billing form or Form CMS-1500. The correct coding is key to submitting valid claims. The proper procedures for coding are listed in Chapter 23

of the Medicare Claims Processing Manual, entitled Fee Schedule Administration and Coding Requirements.

19. CMS maintains the Healthcare Common Procedure Coding System (HCPCS) and publishes coding tables quarterly, listing the codes used by health care providers to be reimbursed for services covered by Medicare and Medicaid. The Current Procedural Terminology ("CPT") code set is published by the AMA and included in the CMS tables. The CPT code books include guidance and instructions on which codes to use and when.

20. The Medicaid Program is a joint state-federal program that provides health benefits for particular groups, such as indigent and disabled individuals. The federal portion of each state's Medicaid payments is based on a state's per capita income. During all relevant times, the Federal Medical Assistance Percentage ("FMAP") for California was 50 percent.

21. Submission of false claims to Medicaid necessarily results in false claims being submitted to California Medicaid because those claims, once processed, are partially paid by the California Department of Health Care Services.

VI. FACTUAL OVERVIEW

22. Dr. Hong began practicing radiation oncology at Eisenhower in July 2017.

23. Dr. Hong was an employee of EMA.

24. From the very beginning of his employment with Eisenhower, Dr. Hong had significant concerns about its billing practices. Dr. Hong's initial concerns related primarily to the lack of documentation that he observed, as well as Eisenhower's billing practices related to particular procedures and activities. Over time, Dr. Hong's concerns grew to include several

other billing, financial, and treatment practices. Dr. Hong's allegations of False Claims Act violations now involve the following general categories:

a. Lack of supervision.

b. Lack of documentation.

c. Improper coding and charges.

d. Improper credentialing and privileging.

e. Improper kickbacks to referring urologists and other physicians.

25. Dr. Hong almost immediately began to notice that some of the coding and billing practices of the office did not follow the guidelines set forth by Medicare and Medicaid.

A. Lack of Required Supervision

26. One of Dr. Hong's concerns regarding Eisenhower was its lack of physician supervision over particular radiation oncology treatments.

27. The 2017 American College of Radiation Oncology (ACRO) Billing and Coding Guide states that "direct supervision is the standard for all hospital outpatient therapeutic services covered and paid by Medicare."

28. Therefore, a qualified physician should supervise all radiation therapy services provided. In addition, within the signature line on the CMS 1500 claim form and the CY 2016 updated —incident to guidelines, services billed were medically necessary and personally supervised by the billing physician… the supervisory responsibility as being more than the capacity to respond to an emergency or to resume treatment that had been interrupted. The provider must be physically present, interruptible and immediately available to reassess the patient and resume treatment as appropriate. This could include modifying treatment as needed

on a non-emergent basis, the ability to redirect or take over performance of the service and issue any additional orders.

29. Supervising physicians should be clinically trained in the specialty they are overseeing and have within their state Scope of Practice the ability to provide the services they are supervising. These requirements alone indicate the supervision for radiation oncology services would only be appropriately provided by a radiation oncologist." Similar guidance is available from the American Society of Radiation Oncology and American College of Radiology.

30. Dr. Hong observed that throughout his employment with Eisenhower, Dr. Monica Khanna would often leave the department early, in the middle of the day, or otherwise become physically not present, not interruptible, or not immediately available.

31. Under Medicare regulations, bills should be submitted with the supervising physician indicated. Upon information and belief, Eisenhower submitted bills for these encounters to Medicare that indicated that Dr. Khanna was the supervising physician when she was not truly present.

32. Dr. Hong spoke with dosimetrist Ronald "Daryl" Watkins about this issue in May 2018. Watkins raised the issue because accurate designation of the supervising physician had been emphasized as important at many of his previous workplaces.

33. In response to concerns about this issue, Dr. Khanna insisted that reporting the proper supervising physician was unnecessary and instructed staff such that these services would continue to be inaccurately recorded.

34. Certain services require greater degrees of supervision than others, with some requiring physician presence. This was not part of departmental protocol for certain procedures until after Eisenhower's billing audit in Winter of 2017/2018.

35. Prior to changes in March 2018, Monica would conduct informed consent for patients undergoing radiation treatment but was not physically present to approve the final product of most simulations (77280, 77285, 77290), which is required.

36. Dr. Khanna was also likely not present to approve imaging for most, if not all, stereotactic radiation treatments. Stereotactic radiation treatments involve precise delivery of extremely high dose radiation treatments. Because of potential danger associated with misadministration of these treatments, physician approval of pre-treatment imaging is required prior to each fraction. Based upon Dr. Hong's review of time stamps relating to treatments and imaging approvals recorded in the department records and verification system, Dr. Hong believes that Dr. Khanna was not present for most of her stereotactic radiation treatments until late 2018.

37. Around the time that physician approval of imaging was made policy in March 2018, Dr. Khanna asked Dr. Hong if he approved images prior to stereotactic treatments, to which he said "always." Dr. Khanna then told Dr. Hong "I usually don't. They do a great job without me," or words to that effect.

38. Dr. Hong was also troubled due to the lack of any radiation oncologist presence whatsoever during some radiation treatments. Eisenhower has two radiation treatment centers, one in Rancho Mirage, and another in La Quinta. La Quinta has an older linear accelerator and treats fewer patients than the Rancho Mirage location. The La Quinta center was predominantly used when the Rancho Mirage linear accelerators had technical issues preventing treatment and for select patients for whom the La Quinta location was more geographically convenient.

39. According to Dr. Robert Johnson, patients were consistently treated at La Quinta without a radiation oncologist present during his tenure from 2012 to 2016, and probably before.

40. Sometime in Fall 2016, Eisenhower halted treatments at La Quinta. Treatments were later resumed and Dr. Johnson was required to be present at La Quinta during all treatments.

41. After registered nurse Dixie Sheffield retired in late 2017, Eisenhower hired nurse practitioner Shawanda Motlof with the stated goal to have her supervise treatments at La Quinta. This would have been inappropriate according to the American Society of Radiation Oncology 2016 Physician Supervision White Paper, because these procedures would be outside of a nurse practitioner's training and scope of practice. Motlof had no oncology experience or radiation-specific training. This ultimately did not occur because Ms. Motlof quickly decided to leave Eisenhower.

B. Lack of Documentation

42. From a billing perspective, medical providers must (1) order a service; (2) provide the service; (3) document that the service was performed; and (4) submit accurate bills for services rendered. For advanced radiation techniques they may also need to provide medical necessity statements.

43. Eisenhower has consistently failed to ensure that these requirements were satisfied.

44. Radiation oncology is a complicated, technical field with a complex care process. Many Eisenhower radiation services have incomplete, inaccurate, or absent orders. Some services were charged for but never provided. Documentation of many services is insufficient or does not exist. Incorrect codes were submitted for many services. Medical justification

statements do not exist for most treatments involving advanced techniques such as 3d-conformal radiotherapy, intensity modulated radiation therapy, stereotactic radiosurgery, stereotactic body radiotherapy, and image-guided radiation therapy.

C. Improper Coding and Charges

45. Dr. Hong also observed billing issues at Eisenhower involving improper coding and charges, leading to false claims being submitted to Medicare and Medicaid.

46. Dr. Khanna "upcodes" most consultation and follow-up visits, which means she charges for a higher (and more expensive) level of care than actually provided.

47. For example, Dr. Khanna told Dr. Hong that she only ever bills level 4 for new patients, and directly instructed him that "all you have to do that is to say you spent 45 minutes with the patient at the end of your note," or words to that effect.

48. Dr. Hong later asked billing consultant Janae Ballard from CodingAID if Dr. Khanna's statement about level 4 was accurate and Ms. Ballard told him that all required elements (history, exam, and medical decision making) must be present in order to bill any given level.

49. Similarly, Dr. Khanna instructed Dr. Hong that all follow-up visits should be charged as level 3.

50. At one point Dr. Hong asked Dr. Khanna if he could adjust the appointments for consults and follow-ups in the electronic medical record to allow easier capture of different levels of service. Dr. Khanna told Dr. Hong no, and that this is the way that Dr. Khanna did things, and that because she is the medical director with over 25 years of experience, Hong must adapt to her system.

51. If a patient receives radiation therapy, there is a series of professional codes for clinical treatment planning (77261, 77262, and 77263). These codes capture the cognitive expertise of the radiation oncologist in designing a course of radiation therapy.

52. The 2017 ACRO Billing and Coding Guide states: "Medicare requires a written treatment plan that has been approved by the physician with the associated date and time. It is also important to note that the documentation of the clinical treatment plan is considered a separately billable service from the evaluation and management service; therefore, it must be separately documented."

53. It further states that "Documentation supporting medical necessity should be legible, maintained in the patient's medical record and made available to Medicare upon request… The clinical treatment plan also provides the radiation oncologist the opportunity to order and document the patient's specific medical necessity for other services, such as special dosimetry (77331), special physics consultation (77370) and a special treatment procedure (77470). This could also include a supporting statement for IGRT and additional imaging procedures."

54. This documentation did not exist until around March of 2018, which includes a lack of medical necessity statements for most cases.

55. After consultation, the next step for patients receiving external beam radiation therapy is simulation. Simulation refers to the process of placing a patient in the treatment position, creating/using devices to maintain said position if necessary, and taking measurements to allow for dose calculation or development of a treatment plan.

56. As an example, patients with breast cancer can be simulated with a breast board, which is a device that allows precise, reproducible placement of the patient's body, breasts, and

arms in space. After the patient is placed in the correct position, a CT scan can be acquired and the resultant product approved by the physician.

57. Simulation is a key procedure that is analogous to a surgeon determining initial patient position prior to draping and cutting. Depending on complexity, simulations can be represented by the codes 77280, 77285, and 77290.

58. At Eisenhower, the orders for simulation procedures were often not complete enough to perform the task and generally did not specify key elements of the procedure such as patient positioning.

59. When Dr. Hong started working at Eisenhower, he quickly proposed improving simulation order templates to include all key details appropriate for each disease site and situation, but he was overruled by Dr. Khanna, who said it was not necessary.

60. Dr. Hong's intent with those suggestions was not to improve compliance, but to increase operational efficiency as such templates help reduce variation, save time for tedious tasks that can be easily standardized, and generally provide more complete and specific instructions which prevent error by helping radiation therapists perform procedures correctly.

61. Documentation for simulation procedures do not appear to have existed at all prior to March 2018 apart from patient photos, which were uploaded and approved well after the patient had started treatment.

62. As previously stated, physician presence at simulation was not required by Eisenhower prior to March 2018 and probably did not occur in most cases apart from skin cancers, where physician presence is essential to determine certain aspects of treatment.

63. In the case of skin cancers, it appears that Eisenhower and Khanna billed complex simulations (77290) for nearly all skin cancers treated with superficial photons or en face

electrons during the tenure of dosimetrist Renato del Oro, even though these do not require a CT scan and would only qualify as simple (77280).

64. There are other instances that Eisenhower and Khanna inappropriately upcoded procedures as complex, such as palliative treatments with simple beam arrangements.

65. Starting January 1, 2014, CT-guidance codes (77014) were bundled into simulation codes (77280, 77285, and 77290), but Eisenhower continued to bill the 77014 codes separately for some time.

66. Starting January 1, 2013, simulation codes (77280, 77285, and 77290) were bundled into the intensity modulated radiation therapy planning codes (77301). See OIG Report No. A-09-16-02033.

67. Nearly all patients undergoing IMRT treatments were charged for a complex CT simulation until around March of 2018.

68. Dr. Hong observed that some patients were also billed for a complex simulation on the first day of treatment, which is unlikely to be legitimate for non-emergent external beam radiation treatments.

69. Part of a simulation is making and using treatment devices (77332, 77333, and 77334). In this context, this refers to different devices that can be used to help the patient precisely achieve and maintain a particular position. This is medically necessary because the accuracy and precision of treatments in targeting tumors and avoiding organs at risk are contingent on the patient being in a reproducible position.

70. If orders were incomplete, devices were used based on inference from the site of treatment (e.g. wing board for lung cancer). Some devices were fabricated without orders, for example, custom headrests for patients with head and neck cancer.

71. Until the simulation note was created in March 2018, there was no documentation of the devices made apart from photos that were uploaded after the patient had started treatment. Some devices, most notably wing and breast boards, pre-cut electron blocks, and pre-made bolus, were also inappropriately billed as complex (77334), when they should be billed as simple or intermediate (77332/77333).

72. After simulation, the next step is treatment planning. The discipline of radiation oncology focuses on the therapeutic use of ionizing radiation to treat cancer. Just as surgical oncologists aim to remove tumors while avoiding damage to adjacent structures, radiation oncologists deliver radiation to areas where tumor cells are known or are likely to reside while minimizing dose to adjacent tissues. The fundamental service provided is controlling the spatial and temporal distribution of ionizing radiation to cause desired biological effects with minimal toxicity.

73. In modern radiation therapy planning, the primary function of the radiation oncologist after simulation is to identify the target to be treated and to specify how much dose needs to go where (target volume coverage goals) as well as how little dose needs to go elsewhere (constraints on organs at risk), and to review the resultant treatment plan.

74. For example, to use the example of a breast cancer, a radiation oncologist could outline the breast after surgery, forming a clinical target volume (CTV). The radiation oncologist would then make a geometric expansion on the CTV to account for setup error and form a planning target volume (PTV). The radiation oncologist should then instruct the dosimetrist, preferably in a written patient-specific planning directive, that he or she should develop a 3D-conformal treatment plan covering the PTV with 50 Gray (Gy) in 25 fractions while keeping the

volume of lung receiving 20 Gy or more less than 15% as well as the average dose to the heart below 2.5 Gy.

75. These are tasks that would be inappropriate for anyone but the radiation oncologist to complete. Planning documents did not exist when Dr. Hong started working at Eisenhower, so he proposed creation of site and context-specific planning directive documentation around the time he first started in July 2017. Dr. Khanna directly instructed him not to generate planning documentation.

76. There were many instances where simple or complex isodose plans (77306 and 77307) were upcoded as complex or 3D conformal treatment plans (77307 and 77295). Per the 2017 ACRO Billing and Coding Guide, "3-D planning is a more complex planning process than standard isodose planning due to the involvement of a contoured tumor volume and surrounding normal critical structure(s)." Many plans billed as 3d conformal do not have a target volume and do not have recorded constraints (e.g. Patient R.R.).

77. In some cases where there is some sort of target volume, the target volume was clearly not used to generate the treatment plan as the plans' isodose distributions are not conformal to the target (e.g. Patient C.W.). In many cases where a target volume exists, the target volume was not generated by Khanna or approved prior to the initiation of treatment planning.

78. Basic dosimetry calculations (77300) are bundled into simple and complex isodose plans (77306 and 77307) but not into 3D-conformal treatment planning (77295), and so Eisenhower and Khanna inappropriately charged additional units of 77300 for simple and complex isodose plans.

79. Treatment devices (77332, 77333, and 77334) are also billed during treatment planning, which in this context refers to beam modifying devices, which are objects placed in the

path of the radiation beam to modify the dose deposition characteristics. For palliative cases, simple devices (77332) were sometimes billed as complex (77334). In cases where there are opposing fields which are mirror images of each other, 2 units were often billed when the appropriate quantity is 1 (e.g. Patient R.J.).

80. Eisenhower transitioned its billing system to EPIC (an electronic medical record system) in July 2017. Eisenhower supposedly has a limited ability to analyze prior claims due to a billing system that has been described to Hong as "convoluted" and "broken" by Curci Cancer Center Chief Administrative Officer Katie Schnaser.

D. Improper Credentialing and Privileging

81. Dr. Khanna trained in the late 80s and early 90s, before CT scanners were routinely available and well before the development of 3D-conformal radiation therapy, intensity-modulated radiation therapy, stereotactic radiosurgery, stereotactic body radiotherapy, and image-guided radiotherapy, and she has not kept up to date with advancements in the field.

82. Dr. Hong repeatedly attempted to protect patients by speaking with Khanna tactfully to improve her treatment plans.

83. Dr. Hong remains concerned that Dr. Khanna's continued ability to practice is a threat to the survival and quality of life of patients under her care. Dr. Hong believes that the care in many of her cases could constitute malpractice.

84. Dr. Khanna relies far too heavily upon the dosimetrists for key aspects of treatment planning. These dosimetrists include Renato del Oro (permanent), John Rodriguez (*locums tenens*), Brock Harnish (*locums tenens*), and Ronald "Daryl" Watkins (permanent).

85. Dr. Khanna relies on the dosimetrists for contouring targets in many of her plans, for knowing appropriate constraints for organs at risk, and for determining whether treatment

plans are acceptable. This would be analogous to a surgeon giving their scrub tech a scalpel, letting them perform the surgery, and then later claiming they performed it themselves. This would not only be fraudulent but in many cases, dangerous.

86. Both Rodriguez and Watkins independently expressed shock to Dr. Hong regarding Khanna's remarkable lack of knowledge. Watkins told Hong that Khanna consistently declined to review key aspects of treatment plans, namely the dose-volume histogram, despite Watkins' repeated attempts and insistence. The dose-volume histogram is a graphical representation of dose to structures and targets that is essential for reviewing most radiation treatment plans.

87. Dr. Hong personally reviewed many of Khanna's prior treatment plans which do not follow any reasonable interpretation of the standard of care and caused harm in the form of increasing the probability of treatment-related toxicity, tumor recurrence, being subjected to resultant salvage treatments, and/or premature death.

88. As an example, Dr. Hong saw a patient in consultation with a solitary brain metastasis and recommended stereotactic radiation therapy to the metastatic tumor. This was a reasonable recommendation and represented the standard of care per National Comprehensive Cancer Network guidelines. This patient had been specifically referred to Dr. Hong by the referring medical oncologist. Khanna was upset that the patient had been referred to Dr. Hong and insisted on seeing the patient herself after the consultation. She proceeded to talk the patient out of receiving treatment.

89. Medicare/Medicaid/VA rules require that providers be appropriately credentialed for providing services. Due to the time at which she received board certification, Khanna is exempt from participating in maintenance of certification. Upon information and belief, Khanna

has had no formal training in modern radiotherapy and clearly did not learn on the job, and is thus unqualified to perform 3D-CRT/IMRT/SBRT/SRS/IGRT. Therefore, Khanna was improperly credentialed by EMA and inappropriately granted privileges by EMC in violation of payor regulations.

90. For example, for stereotactic radiosurgery, Eisenhower requires sufficient training during residency or the equivalent and having treated at least 6 cases in the prior 2 years.

91. Upon information and belief, Khanna made a false statement when requesting privileges for stereotactic radiosurgery on 9/26/2016. In her application, she stated that she had treated 10 cases of stereotactic radiosurgery in the preceding 2 years. Based on the department schedule, she only performed two cases in that time frame.

92. The failure of Eisenhower Medical Associates and the Eisenhower medical staff to perform due diligence and verify physician qualifications directly led to patient harm as can be seen in the case of Patient C.C., who had a disturbingly large amount of normal brain treated with ablative radiation.

93. Other examples of Khanna's lack of competence impacting patient care include planning for anal, brain, head and neck, pancreatic, and prostate cancers. (Patients P.K., R.J., G.T., J.S., and J.C.). These are not isolated examples.

94. There are issues with charges for IMRT plans (77301) and IMRT MLC devices (77338). Khanna often did not delineate target volumes herself, did not provide specific dose constraints for targets or organs at risk, did not provide medical necessity statements, and treatment plans meeting prescribed dose constraints could not be generated as the constraints did not exist. These are all required elements when charging for IMRT. In addition, for some breast

plans, "forward-planned IMRT" was inappropriately billed as IMRT when per AMA definition and Medicare LCDs they are by definition 3d conformal (e.g. patient J.W.).

95. Eisenhower often billed code 77399 for "image fusion," which is not an acceptable use for that code. There is no documentation for this putative service. Image fusion can only be billed when performed by a medical physicist in response to a specific request from a radiation oncologist in the form of a special medical physics consult (77370).

96. Special dosimetry services (77331) were routinely performed for nearly all non-IMRT cases. The description of 77331 in the 2017 ACRO Billing and Coding Guide is as follows: "Special dosimetry (example TLD, micro-dosimetry, diode), only when prescribed by the treating physician … Documentation for this service includes physician orders, medical necessity and documentation of the measurement, including a review by the physician. Payers also specify the physician must define the type of special dosimetry to be performed." Orders and medical necessity statements do not exist. The date of service for when services were charged often did not match with physician approval, which would represent the appropriate date of service.

97. Prescriptions are the oncologist's order for delivery of radiation treatments. Treatment prescriptions were often incomplete—lacking a target volume/isodose line/prescription point, energy level, modality, technique, frequency, target volume coverage goals, organ at risk constraints, and/or image guidance orders and instructions. Guidelines for prescriptions can be seen in the American College of Radiology-American Society for Radiation Oncology Practice Parameter for Radiation Oncology and the American Society for Radiation Oncology "Standardizing dose prescriptions" White Paper.

98. Prior to the first treatment of many plans a procedure is performed that is known as a machine verification or dry run. The patient is taken to the linear accelerator and placed in the treatment position with appropriate devices. Images are acquired to confirm the treatment position and the setup is confirmed by the treating radiation oncologist. This procedure is billed as a simple simulation (77280) and requires documentation and presence of the radiation oncologist. This procedure was never documented and physician presence was not required until March of 2018. The only evidence that this procedure was performed would be approval of the acquired images at a later time, which would not prove that the physician was there at the time of the service. Per the 2017 ACRO Billing and Coding Guide, "Documentation of the verification simulation includes the images of each field with the corresponding blocking in place, and a note outlining all of the pre-treatment parameters verified. The radiation oncologist must review and approve all images, including the verification simulation note, prior to beam on of the first treatment field." This procedure was not allowed to be charged with IMRT plans prior to April 1, 2016, or after January 1, 2017, although it was routinely charged.

99. Special treatment procedure (77470) is a code which can capture extra work performed by the physician during a course of radiation therapy. The most common example for this code would be for extra work monitoring hematologic side effects of concurrent chemotherapy. Some patients receiving radiation therapy receive chemotherapy at the same time, the combination of which can cause significant drops in the levels of red and white blood cells as well as platelets, and thus requiring periodic evaluations of the patient's complete blood counts. Billing this code would require a medical justification statement and proof of extra work performed by the physician. An example of sufficient documentation would be medical necessity statements along with continuous notations by the physician that periodic labs were

contemporaneously reviewed. 77470 was identified as a potential source of extra revenue during the billing audit by CodingAID. Eisenhower's response was to have registered nurse Bo Dunn identify potential cases, generate the justifying documentation, and charge the code without the documentation or involvement of the supervising physician.

100. Dunn expressed to Dr. Hong that she was uncomfortable with this arrangement as she felt it was inappropriate.

101. Starting January 1, 2015, IMRT coding was divided into simple and complex, with simple consisting of breast and prostate treatments, and complex consisting of all other sites. Eisenhower billed nearly all breast and prostate cancer IMRT cases as complex until Fall 2018.

102. Stereotactic radiation treatments have a variety of billing codes, reflecting first versus later treatments, intracranial vs. extracranial, and robotic vs. non-robotic. Stereotactic treatments were often captured using incorrect codes. This is likely due to inadequate training of radiation therapists and improper setup of the electronic medical record. For Khanna's cases, supervision requirements were not met until recently.

103. Khanna also treated lung cancer with 6 fraction treatments that she billed incorrectly as SBRT. By definition, courses of stereotactic radiation therapy cannot exceed 5 treatments. Statements of medical necessity for stereotactic radiation were lacking until recently.

104. Many radiation treatments use image guidance, which refers to acquisition of images on the treatment machine prior to individual treatments to align the target and/or confirm filling status of organs such as the rectum or bladder. Although this was often performed at Eisenhower, it was not billed routinely until recently. Orders for image guidance were often missing from prescriptions. When they were billed, cone beam CTs (77014) were often

incorrectly billed as stereoscopic x-rays (G6002). Cone beam CTs were occasionally billed with both technical and professional components, although after January 1, 2015, the technical component of IGRT was bundled into IMRT treatment codes. IGRT has always been bundled with stereotactic treatment codes. Medical necessity statements for image-guided radiotherapy were not routinely used until March 2018.

105. In regards to image guidance, Khanna attempted to have nurse practitioner Shawanda Motlof review IGRT images for her patients. The radiation oncologist is the only appropriate provider for image guided radiation therapy. Motlof refused to perform this task.

E. Improper kickbacks to referring urologists and other physicians.

106. Fiducial markers are small pieces of metal that can be implanted into patients receiving irradiation to the prostate and other areas in order to increase accuracy of treatment.

107. Eisenhower provided these fiducial markers to referring urologists free of charge.

108. By doing this, Eisenhower effectively gave referring providers several hundred dollars, as well as the opportunity to perform and bill more for ultrasounds and implantation procedures.

109. This practice dated to at least 2012, and likely earlier.

110. Front office manager Marie Lucas Lopez primarily handled the logistics surrounding delivery of these fiducials.

111. On July 24, 2017, Dr. Hong sent an email to Monica and Curci Cancer Center Chief Administrative Officer Katie Schnaser advising them of possible Stark Law violations when giving referring urologists fiducial markers. In retrospect, the relationships in question are better described as kickbacks as they involve the provision of goods of significant value to influence the behavior of referring physicians.

F. Dr. Hong raised serious concerns about Eisenhower billing practices.

112. On August 9, 2017, Dr. Hong met with biller Chandra Dunn at 1 p.m.

113. During this conversation, Dr. Hong observed that the process of pre-authorization was flawed. After a physician verbally instructed front office staff as to the site they intended to treat, treatment planning technique, and total number of fractions, they would look-up a set of charges in a Word document and pass them to billing for approval. The sets of charges appeared outdated and incorrect. Chandra and front office manager Marie Lucas Lopez were unsure of when the document had last been updated and where it originated from.

114. On August 11, 2017, Dr. Hong met with Curci Cancer Center Chief Administrative Officer Katie Schnaser at 8:15 a.m. and again expressed his concerns verbally, with detail about serious issues that he observed with pre-authorization of charges and charge capture. Dr. Hong explained that he believed that the radiation oncology charge capture process was error prone and that many procedures lacked appropriate documentation. Dr. Hong requested that he be provided with the actual codes sent to payors in his name. These were never provided to him.

115. Throughout Summer 2017, Dr. Hong noticed that many of Dr. Khanna's consultations were incomplete and that some her treatment plans appeared to deviate from standards.

116. Dr. Hong discussed this with *locums tenens* dosimetrist John Rodriguez, who told him that Dr. Khanna did not know very much with regard to treatment planning.

117. Over time, Dr. Hong gained a better appreciation of Dr. Khanna's lack of knowledge essential for providing modern radiation services.

118. Dr. Hong began having regular episodes of conflict with Dr. Khanna, primarily involving the way that Dr. Hong wanted to treat his patients. Dr. Khanna routinely berated Dr. Hong behind closed doors and out of earshot because his decisions and management style differed from hers.

119. Dr. Khanna's expectation was that Dr. Hong should emulate her patterns of care, which Dr. Hong considered unethical and inappropriate. Dr. Hong refused to do so.

120. Dr. Hong met with Curci Cancer Center Medical Director Dr. Steven Plaxe frequently throughout his employment. Dr. Plaxe held a meeting for cancer center physicians most weeks for which Dr. Hong was often the only attendee.

121. Dr. Hong repeatedly told Dr. Plaxe about his conflicts with Dr. Khanna and her abusive behavior, improper billing, interference with professional autonomy, and the generally bad health care provided by Dr. Khanna.

122. Dr. Plaxe told Dr. Hong that with regard to the workplace conflicts, abuse, and the generally hostile work environment, nothing would be done and that Dr. Hong should just listen to Dr. Khanna.

123. With regard to billing, Dr. Plaxe told Dr. Hong that "they" were working on it and that "it's a process."

124. Regarding bad care, Dr. Plaxe told Dr. Hong that that was a conversation for him to have with Dr. Khanna behind closed doors.

125. In March 2018, Taleah Tatum started working as the new radiation oncology department manager. Dr. Hong quickly filled her in on the billing issues, which she had already noticed on her own. Tatum was tasked with improving billing practices in the department.

126. Starting in March 2018, Eisenhower started making changes to departmental processes and documentation.

127. From May 15 to June 1, 2018, Dr. Hong was away from the department to take oral board examinations and subsequent vacation. He returned from vacation on June 4, 2018. Monica told him that he had a routine end of year meeting on June 7. Dr. Hong assumed that it involved his potential discretionary bonus of 10% of annual gross salary, which was supposed to be based on quality of care and objective measures of performance.

128. On June 6, 2018, Monica called at least one referring physician. Dr. Lance Walsh, a urologist, and told him that Dr. Hong was being terminated for getting along poorly with referring physicians. Dr. Walsh later told Dr. Hong that he told Monica that that was inconsistent with his personal experience with Dr. Hong, that he had a favorable opinion of Dr. Hong as a person and clinician, and that he had written an email in Hong's defense to Eisenhower Health Chief Operating Officer Martin "Marty" Massiello.

129. On June 7, 2018, Dr. Hong attended a meeting with Monica and Eisenhower Medical Associates CEO Scott Fitzgerald at 2 p.m.

130. To Hong's surprise, Fitzgerald read out a termination letter. Khanna told Hong that he should go to an academic center, since "I'd do better there." Hong had never been spoken to about his performance by anyone other than Monica.

131. Dr. Hong requested a meeting with Curci Cancer Center Medical Director Dr. Steven Plaxe later that afternoon where Dr. Plaxe told him that he was an excellent physician with a sterling reputation, but that there was a personality fit problem. Dr. Plaxe told Dr. Hong that he was "ten years ahead of the institution." Dr. Hong asked Dr. Plaxe whether my claims

about Monica's medical care and bad behavior been investigated or reported and did not receive an answer.

132. Many physicians later told Dr. Hong that Khanna was politically protected by Eisenhower administration because her husband, interventional cardiologist Dr. Puneet Khanna, is responsible for directly and indirectly generating large amounts of revenue as a busy clinician and due to his influence within independent medical group Eisenhower Desert Cardiology Center.

133. On June 11, 2018, department manager Taleah Tatum put in her two weeks' notice. Tatum told Dr. Hong that she expressed concerns about Khanna to Katie Schnaser at length, who encouraged her to frame her departure as a personal decision independent of Khanna.

134. Tatum told Dr. Hong that she was told by the billing consultant Janae Ballard that she should not submit certain claims from January to April 2018 that had known poor documentation, as they would be fraudulent claims. Tatum said she was instructed by Katie to fix the documentation and dates of service so they could be submitted, and that it was okay because they had provided the service.

135. On July 25, 2018, Dr. Hong had a meeting with Dr. Steven Plaxe and Martin "Marty" Massiello at their request. At this meeting, Dr. Plaxe asked Dr. Hong to tell Mr. Massiello share his opinions involving department billing, documentation, and compliance, issues revolving around staffing in the department, and Dr. Khanna's failure to practice good medicine.

136. Dr. Hong expressed the opinion that the quality of Dr. Khanna's care does not meet standards and substantially increases the probability of tumor recurrence and significant

toxicity and tumor recurrence which could lead to impaired quality of life and/or premature death.

137. Massiello thanked Dr. Hong for his input and asked him to be professional when speaking with the medical staff.

138. On August 11, 2018, Hong performed an inpatient consultation for a patient C.W., who had a solitary brain metastasis from lung cancer. C.W. had previously been Dr. Khanna's patient, but C.W. told Dr. Hong that she absolutely refused to be seen by Dr. Khanna because during her previous course of radiation Dr. Khanna had spoken to her and her husband in an inappropriately aggressive and demeaning manner on multiple episodes, ultimately leading them to complain to cancer center administration and transferring care to Dr. Robert Johnson. Dr. Hong noted that C.W.'s treatment plan was inappropriately upcoded from complex to 3d conformal, resulting in false charges to Medicare.

VII. Falsity

139. Eisenhower submitted false claims to the U.S. Government for payment and created false records material to false claims for payment in several ways.

140. The Medicare and Medicaid claim forms and accompanying billing records completed by Eisenhower contain improper billing codes, used to seek a higher rate of reimbursement from Medicare and Medicaid for services that Eisenhower did not actually provide.

141. Eisenhower also falsely certified compliance with applicable laws and regulations, to include the Anti-Kickback Statute.

VIII. Scienter

142. Defendants knew that the coding and drug reimbursement claims on the Medicare and Medicaid claim forms were false in the following ways:

a. EMC, EMA, and Khanna knew that that the Medicare and Medicaid claim forms and billing records contained false CPT codes;

b. EMC, EMA, and Khanna knew that the Medicare and Medicaid claim forms and billing records contained multiple CPT codes when multiple services were not performed; and

c. EMC, EMA, and Khanna knew that the Medicare and Medicaid reimbursement forms and billing records were false because the treatment was not provided by a properly credentialed and competent health care provider.

143. Based upon the Defendants' specific knowledge outlined above with regards to Eisenhower and Khanna's improper coding and billing practices, Eisenhower and Khanna had actual knowledge, were deliberately ignorant, or recklessly disregarded the truth in making false claims for payment to Medicare and Medicaid or in creating false records material to false claims to Medicare and Medicaid.

IX. Materiality

144. The false statements contained in the billing records and the Medicare and Medicaid claim forms were capable of influencing Medicare and Medicaid's funding decisions in the following ways:

a. A false code could influence the rate of Medicare and Medicaid's reimbursement because the CPT codes are reimbursed at a set rate, determined by CMS; and

b. The false claim for reimbursement for multiple healthcare services, based on multiple codes, could influence the amount of Medicare and Medicaid's reimbursement because multiple codes are allowed when proper and will be reimbursed at the set rate, so Medicare and Medicaid rely on the healthcare provider's representations in order to pay out the proper reimbursement.

X. Damages

145. As a result of the knowing submission of false statements and the creation of false medical records, the Defendants induced Medicare and Medicaid to pay out claims for E/M and radiation therapy services that were not rendered or were coded at a heightened rate, thereby damaging Medicare and Medicaid in an amount to be determined at trial.

XI. Causes of Action

Count I:
False Claims in Medicare and Medicaid PPS Claims; 31 U.S.C. § 3729(a)(1)(A)
(Against All Defendants)

146. Relator incorporates all foregoing paragraphs as if fully set forth in Count I.

147. The United States and Relator Hong seek relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

148. Defendants EMC, EMA, and Khanna submitted or caused to be submitted false claims for payment to CMS. These false claims for payment include, but are not limited to, the false coding and billing information in the CMS-1500 forms and/or electronic 837P forms submitted to Medicare and Medicaid from at least 2012 to present.

149. Defendants EMC, EMA, and Khanna knew that the claims were false when made in that they had actual knowledge that the claims were false, remained deliberately ignorant as to the falsity of the claims, or recklessly disregarded the falsity in the claims.

150. The false statements contained in the false claims for payment were material because they could influence Medicare and Medicaid's funding decision.

151. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus civil penalties for each violation.

Count II:
False Records Material to Medicare and Medicaid PPS Claims; 31 U.S.C. § 3729(a)(1)(B)
(Against All Defendants)

152. Relator incorporates all foregoing paragraphs as if fully set forth in Count Two.

153. Defendants EMC, EMA, and Khanna submitted or caused to be submitted false claims for payment to CMS.

154. Defendants EMC, EMA, and Khanna created false records material to the false claims to Medicare and Medicaid. These false records include, but are not limited to, false CMS-1500 and 837P forms, and false billing records.

155. These false records were material to the false claims submitted by Defendants to Medicare and Medicaid for payment as to the above-mentioned patients from at least 2012 to present.

156. These records were false when made, and the Defendants knew that they were false when made.

157. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus civil penalties for each violation.

Count III:
Violations of California False Claims Act;
False or Fraudulent Claims
(Cal. Gov't Code § 12651(a)(1))
(Against All Defendants)

158. Relator incorporates the foregoing paragraphs as if fully set forth in Count III.

159. Defendants EMC, EMA, and Khanna knowingly submitted, or caused to be presented, false claims to California Medicaid.

160. As a result of this conduct, Defendants caused the State of California to suffer actual damages in an amount to be determined at trial.

Count IV:
Violations of California False Claims Act;
False Records or Statements
(Cal. Gov't Code § 12651(a)(2))
(Against All Defendants)

161. Relator incorporates all foregoing paragraphs as if fully set forth in Count IV.

162. Defendants EMC, EMA, and Khanna knowingly made, used, or caused to be made or used, false records or statements in connection with false claims to California Medicaid.

163. As a result of this conduct, Defendants caused the State of California to suffer actual damages in an amount to be determined at trial.

XII. Prayer for Relief

WHEREFORE, Relator, on behalf of the United States and the State of California, prays that judgment be entered in her favor and against Defendants as follows:

1. That Defendants pay the United States and the State of California triple the amount of its damages to be determined, plus the appropriate civil penalties for each false claim, statement, or record;

2. That the Relator be awarded all reasonable attorneys' fees and costs, pursuant to 31 U.S.C. § 3730(d)(1), 31 U.S.C. § 3730(d)(2), and Cal. Gov't Code § 12652(g)(8);

3. That in the event that the United States and/or the State of California proceeds with this action, the Relator, for bringing this action, be awarded an amount of at least fifteen percent but not more than twenty five percent of the proceeds of any award or the settlement for the United States and/or at least fifteen percent but not more than thirty three percent for any California award or settlement;

4. That in the event that the United States and/or the State of California does not proceed with this action, the Relator be awarded an amount that the Court decides is reasonable for collecting the civil penalty and damages, which shall not be less than twenty five percent nor more than thirty percent of the proceeds of any award or settlement for the United States and/or

not less than 25 percent or more than fifty percent of any award or settlement for the State of California;

5. That the Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and Cal. Gov't Code § 12652;

6. That the Relator be awarded pre-judgment and post-judgment interest; and

7. The Court award such other and further relief as is just, equitable, and proper.

Relator requests a jury on all issues so triable.

November 27, 2018

Respectfully submitted,

DAVID HONG

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